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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,079	07/22/2003	Stephen Solomon	03420/LH	9463

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EXAMINER

VRETTAKOS, PETER J

ART UNIT	PAPER NUMBER
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3739

DATE MAILED: 07/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

6

Office Action Summary	Application No. 10/625,079	Applicant(s) SOLOMON, STEPHEN	
	Examiner Peter J. Vrettakos	Art Unit 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 6-28-05.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The Applicant has elected without traverse claims 1-15, 6-28-05.

Claims 16-19 were amended to depend from claim 1.

Claims 1-19 are pending and rejected below.

Drawings

New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because manually drafted figures are informal. Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 19 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Office cannot determine how each instrument in claim 19 can include a same signature (in multiple signature types?) when in claim 18, from which 19 depends, it is claimed that each instrument has a different signature. (It seems that claim 18

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language precludes claim 19 language with regards to different/same instrument signatures).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-2, 4-12, and 16-19 are rejected under 35 U.S.C. 102(e) as being anticipated by Rittman, III et al. (6,575,969).

Independent claim 1 (all parentheticals and comments not claim language refer to Rittman)

A method for ablating or irradiating a tumor (1102; see figure 11) in a body while protecting a nearby structure (1115; col. 30:20-25) from the effects of the ablation, comprising the steps of: inserting an ablation device (1103-4) to a location in the body proximate the tumor (depicted in figure 11), the ablation device having at least one ablation source (1124); interposing an ablation shield (1116) between the tumor (1102) and the nearby structure (1115); and then activating the ablation source to ablate the tumor while the nearby structure (1115) is shielded (col. 30:20-25) by the ablation shield (1116).

Note: in the art of electrosurgical devices – at least in patent law, ablation “sources” are typically not electrodes as disclosed by the Applicant but instead are an external console/control unit to which electrodes are attached. For example, see col. 29:64-66.

Dependent claims

Re: claim 2: The method of claim 1, further comprising the steps of: imaging at least a region including and surrounding the tumor; and guiding the ablation device toward the tumor based on the imaging. See col. 30:40-43, figures 6,8, and 9.

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Re: claim 4: The method of claim 1, wherein the ablation shield is interposed percutaneously. The patent makes numerous references to percutaneous entry of the patented electrode structures and infers percutaneous ("manmade") entry of 1116 ("shield") in col. 29:47-59)

Re: claim 5: The method of claim 1, further comprising the steps of: imaging at least a region including and surrounding the tumor and the nearby structure; and guiding the ablation shield to a position between the tumor and the nearby structure based on the imaging. See col. 30:40-43, figures 6,8, and 9.

Re: claim 6: The method of claim 1, further comprising the steps of: imaging at least a region including and surrounding the tumor and the nearby structure; guiding the ablation device toward the tumor based on the imaging; and guiding the ablation shield to a position between the tumor and the nearby structure based on the imaging. See col. 30:40-43, figures 6,8, and 9.

Re: claim 7: The method of claim 1, wherein the ablation shield is a balloon (col. 29:55-60).

Re: claim 8: The method of claim 7, further comprising the step of inflating (col. 29:55-60; col. 30:20-25) the balloon with a fluid after the balloon is interposed between the

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tumor and the nearby structure and prior to activation (inherent to permit the protective effect of 1116) of the at least one ablation source (1124).

Re: claim 9: The method of claim 8, further comprising the step of selecting the fluid to inflate the balloon from a group consisting of air, carbon dioxide and deionized water.

Rittman discloses that shield element 1116 is fluid-filled (col. 29:57), which anticipates the gases that make up "air".

Re: claim 10: The method of claim 8, further comprising the step of selecting the fluid based on the type of ablation source. Presupposing that element is filled with "air", it can be reasonably asserted that the related cooling supply (1128), as well as the air from which it supplies, was chosen in light of the ablation source type (RF), which is well-known to generate heat during lesion creation. In other words, the cooled air was chosen to minimize RF related heat generation to protect untargeted tissue (col. 30:20-35).

Re: claim 11: The method of claim 1, further comprising the step of constructing the ablation shield to increase a distance between the tumor and the nearby structure when interposed therebetween (see figure 11 - the inflation of 1116 inherently presses up against 1115 causing an increase in the distance between 1102 and 1115).

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Re: claim 12: The method of claim 1, further comprising the step of constructing the ablation shield from a material ("possibly insulated over much of its surface" col. 29:56-60) which serves as a shielding material to counteract the effects of the at least one ablation source.

Re: claim 16: The method of claim 1, wherein treatment of the tumor requires multiple, sequential treatments and the method further comprises: marking the area of the tumor treated by the ablation; and performing at least one subsequent treatment on the tumor based on the marked area of the tumor. Markers and "post thermosurgery monitoring", inter alia disclosed col. 31:25-61.

Re: claim 17: The method of claim 16, wherein the ablation and the subsequent treatment performed on the tumor are radiofrequency ablations (col 31:45) performed using a needle probe as the ablation device and the step of marking the area of the tumor comprises placing a radio-opaque material at a location at ends of wires ("tipped electrodes", col. 31:54) of the needle probe.

Re: claim 18: The method of claim 1 wherein each instrument used to perform the ablation is provided with a different signature that is visible (figure 6, 8, and 9) during imaging performed during the ablation. See col. 13: 33 through col. 16: 37 for a comprehensive review on the power of the PC (611) disclosed not only in figure 6 but

also in analogous figures 8 and 9, anticipating the Applicant's claim of viewing instrument signatures during ablation.

Re: claim 19: The method of claim 18, wherein each said instrument is provided with the same signature in multiple signature types such that the same signature is visible (figure 6, 8, and 9) using multiple imaging modalities. See col. 13: 33 through col. 16: 37 for a comprehensive review on the power of the PC (611) disclosed not only in figure 6 but also in analogous figures 8 and 9, anticipating the Applicant's claim of viewing instrument signatures (**same or different**) during ablation.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rittman (6,575,969) in view of Gough et al. (5,928,229).

*Rittman neglects to **expressly** disclose a device in the context claimed by the Applicant with a plurality of wires that emit RF from their tips. Rittman does, however,*

disclose that the patented RF device can be configured many different ways. See col. 31:44-57.

Gough discloses an analogous (to Rittman 1103-4) device (see figures 3-7) with a plurality of wires being activated to emit radio-frequency current from their tips to create heat to ablate a tumor (28).

Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to modify Rittman in view of Gough by including a plurality of wires into the ablation device. The motivation would be to permit different ablation geometries (flexible wires afford this) for tumors of different geometries and sizes as posited by Gough in col. 8:15-17.

Claims 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rittman (6,575,969) in view of Chin (5,800,540).

*Rittman neglects to **expressly** disclose a device in the context claimed by the Applicant with a fan retractor.*

Chin discloses an analogous (to Rittman 1116) a fan retractor (figure 5c 500). Element 500 has a balloon (504) just like Rittman 1116 but also has fanning extensions (510, col. 5:54-63) to spread apart adjacent tissue. Note that the extensions are suggestively made of insulting material (silicone rubber, col. 5:67) and would not by

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their presence conduct the heat generated by 1103-4 if used in Rittman instead of Rittman 1116.

Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to modify Rittman in view of Chin by including a fan retractor. The motivation would be to further separate targeted tissue from non-targeted tissue.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Ingle et al. (6,629,535).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter J. Vrettakos whose telephone number is 571-272-4775. The examiner can normally be reached on M-F 9-6.

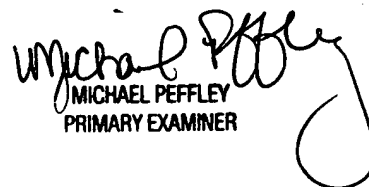
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pete Vrettakos
July 4, 2005

PV


MICHAEL PEFFLEY
PRIMARY EXAMINER